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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/499,423	07/07/1995	CAREY V. CAMPBELL	MP/84	2478

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
11/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/499,423	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9,10,20-23,26 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7,9,10,20-23,26 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/10 has been entered.

Response to Amendment

The declaration under 37 CFR 1.132 filed 10/22/10 is insufficient to overcome the rejection of claims 1,3-7,9,10,20,23,26,28-30 based upon Myers et al. (5628782) as set forth in the last Office action because: Applicant states the prior art tube may be the same material, but can possess different properties. While the Examiner acknowledges that there is some merit to this statement, it must be noted that in order for the claims to distinguish there must be sufficient structure for the claimed function to occur. Applicant provides no structural distinction other than suggesting the prior art tube and claimed tube are engineered differently. A comparison of methods of manufacture with the prior art does NOT serve to resolve the issue of concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not

governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). Additionally, no factual evidence is provided to show the prior art tube of Myers '782 tested under the same pressure claimed would not possess the claimed functional capability. If a patent teaches or suggests the claimed invention, an affidavit or declaration by patentee that he or she did not intend the disclosed invention to be used as claimed by applicant is immaterial. In re Pio, 217 F.2d 956, 104 USPQ 177 (CCPA 1954). Thus, Applicant's argument that the '782 graft is used differently is not persuasive.

Applicant also argues against Tu '276 stating the prior art device provides a compliant graft that would not have a distensibility of at least 100%. However, no structural distinction has been presented to differentiate the Tu device against the claimed PTFE tube, except for an argument that the Tu device does not dilate analogous to the claimed tube. Because the Patent & Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed invention or subject matter is unobvious, the examiner properly shifts the burden to Applicants to show that unobvious differences exist, *Ex parte Phillips*, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93). An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). It cannot be said Applicant has provided any factual evidence that a tube disclosed by Tu '276

does not possess the same distensibility as that claimed since they were not tested under the same claimed "pressures" subjected thereto.

Claim Objections

Claims 20-23 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims depend from a canceled claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

Claim 30 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim recites the “liner covers an anastomosis” and is therefore positively claiming a living tissue, i.e. the vessel of which a graft is attached to form an anastomosis. The living matter of the present invention is not the result of human intervention; it is of nature, which has been held not patentable. It is suggested to amend the claim to recite "the liner is adapted to cover an anastomosis”. An anastomosis is known or considered a repair location within a patient and thus the claim implies the invention is implanted within the patient.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3-7,9,10,20,23,26,28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Myers et al. (5628782). The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. Fig. 5 shows a tube **11** covered with one or more layers of film **17**. Myers et al. disclose the tube is porous PTFE for a graft, col. 3, lines 14,59,60. Myers et al. additionally disclose the film covering the tube is porous PTFE, col. 4, lines 47-53. The use of "substantially unchanged" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. The examiner asserts that the claimed physical property of the tube (in this case, a substantially unchanged second circumference upon expansion 100%) is present in the prior art material to some extent even though not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Since the material of the tube is the same as what is being claimed, the blood liner inherently possesses the same unchanged second circumference in response to internal pressure as the

Applicant's claimed blood liner tube. Regarding claims 3,4,15,16 Myers et al. also disclose the liner comprises a wall with a thickness less than 0.25mm and can be about 0.1mm thick, col. 15, lines 50,51. With respect to claim 5, PTFE inherently possesses nodes interconnected by fibrils. Regarding claims 6,7, Myers disclose that films can be applied a helical layers about the tube, col. 4, lines 55-58. Regarding claim 9, Myers also discloses the film is thermally bonded to the tube, col. 19, lines 1-14. With respect to claim 29, the liner can be a living blood vessel, col. 3, lines 59-62. Regarding claim 30, Myers discloses an anastomosis can be a site of repair, col. 14, lines 11-37.

Claims 1,5,20,22,23,26,28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Tu et al. (5061276). Tu et al. disclose (col. 12, lines 20,21) a tube with an outer covering, Fig. 2. Tu also discloses the device can be used as a graft, col. 4, lines 53-55. Tu additionally discloses the tube is porous, col. 3, lines 4-6. Tu discloses the graft tube is made of polytetrafluoroethylene and has a covering of "essentially" polytetrafluoroethylene, col. 3, lines 45,46, abstract. Please note that the Examiner is interpreting "essentially" as a comprising clause that does not exclude other materials. However, it is understood that a large amount can be understood to be encompassed by this. Tu does disclose that when a blend of PTFE is used that the majority is 95% PTFE (col. 14, lines 15-20) and can thus be considered "essentially" PTFE. Tu et al. disclose the graft can be sutured to a conduit, col. 5, lines 55-63. Tu also discloses the graft circumference increases as a result of the blood pressure, col. 5, lines 46-48. Tu additionally discloses the tube can be expanded such that the second

circumference (10mm) is at least 100% larger than the tube's original circumference (4mm) prior to the application of internal pressure, col. 10, lines 34-38. The polytetrafluoroethylene tube is disclosed as having a microstructure of nodes interconnected by fibrils, col. 7, lines 19-22. The circumference is fully capable of being increased by inflating a balloon. Tu also discloses the tube is placed on a tapered mandrel such that it forms a tapered end with a larger circumference at one end and a smaller second circumference at an opposing end, col. 10, lines 33-35. Because the same materials as claimed are disclosed by the prior art, the examiner asserts that the claimed physical properties are present in the prior art material to some extent even though they are not explicitly recited. Therefore, the examiner hereby burdens the applicant to show that these properties are not present in the prior art. Regarding claim 27, it can be construed that an interior liner is present on the graft when multiple layers of PTFE are used, col. 3, lines 35-38.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6,7,9,10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Eilentropp (4791966). Tu et al. is explained supra. Tu also discloses (col. 11, lines 7-11,col. 12, lines 1-4) that layers of film applied to the tube are helical. However, Tu et al. do not explicitly disclose the PTFE layers are helical. Eilentropp teaches (Fig. 5) that PTFE film

(abstract) can be applied helically about a tube. Eilentropp also teaches that helically wrapping prevents leakage, col. 7, line 68, col. 8, lines 1-3. Therefore, it would have been obvious to one of ordinary skill in the art to apply the PTFE layers helically as taught by Eilentropp about the tube of Tu et al. such that it improves its compatibility and resistance to leakage.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Hughes et al. (4728328). Tu et al. is explained supra. However, Tu does not disclose a tube that is branched with three ends. Hughes et al. teach a tubular prosthesis that is branched with three ends, Fig. 12. It would have been obvious to one of ordinary skill in the art to use the branched tubular form as taught by Hughes with the prosthesis of Tu et al. in a vessel such as the trachea requiring replacement to the two bronchi.

Claims 3,4,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu et al. '276 in view of Lee (5123917). Tu et al. is explained as before. However, Tu fails to disclose the wall thickness to be less than 0.1mm or use of a stent used to secure the graft to a conduit. Lee teaches that the thickness of the graft equal to about 0.1mm, col. 5, lines 56-59. Lee additionally teaches (col. 5, lines 25-31) a stent is used to secure a graft to a blood conduit, Figs. 1,4. Lee also teaches the stent is used to provide some stiffness to the graft to support the vessel, col. 3, lines 5-9,20-24. It would have been obvious to one of ordinary skill in the art to utilize a stent or stents as taught by Lee in the graft of Tu et al. such that it provides greater support to the vessel it is implanted in. Additionally, the use of a thickness of about 0.1mm for the wall of the graft as taught by Lee in the

implant of Tu et al. provides a flexible and small profile for easier delivery to the implantation site.

Response to Arguments

Applicant's arguments filed 10/22/10 have been fully considered but they are not persuasive. Applicants' argue that the Myers' device is not necessarily produced or engineered in the same way the claimed invention is. A comparison of the method of manufacture with the prior art manufacturing method does NOT serve to resolve the issue of concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). Applicants admit, pages 6,7 of arguments that the same materials are used in the claimed invention as in Myers '782 graft, but argue that Myers et al. have a different distensibility, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The arguments clearly provide no structural distinction between the claimed structure and the Myers graft tube.

Applicants further argue claims 3,4 individually stating Myers does not disclose the graft tube wall has the claimed thickness. Applicants state there are

other elements possessing the claimed wall thickness and not the liner. However, it is noted that Applicants use the transition phrase “comprising” in claim 1 from which claims 3,4 depend which does not limit the element claimed to be specifically the liner because claims 3 and 4 just recite “a wall” with the claimed thickness dimensions without specifying the element to further define. Thus, Myers can be said to clearly meet the claim requirements.

Applicants also argue claim 29 individually stating the Myers reference does not disclose the blood conduit being a living vessel. As mentioned above, the transition phrase in claim 1 of "comprising" is interpreted that elements of the device include the claimed feature. Thus, since Myers disclose a product including a living blood vessel, it can be said to meet the claim.

In response to applicant's argument that claim 30 is not met by Myers et al. ‘782 stating the claim requires the liner to cover an anastomosis, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicants argue the rejection of claims over Tu et al. (5061276) asserting that Tu suggests an elastomer with the ePTFE and is thus not “essentially” PTFE. Applicants are reminded that MPEP 2111.03 states that:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising."

Since Applicants use "essentially" in the claims, the claims clearly do not exclude additional components or material not required by the claims. First, though it must be noted that **Tu et al. did state that PTFE can be used solely of a PTFE tube and PTFE wrapped about it to thus provide a film, col. 3, lines 32,33,43-46.** Thus, the combination PTFE with an elastomer is just one of another embodiment disclosed by Tu et al. and in interpreting the term "essentially" it can be said to define an element or material by a large amount but does not require that element or material to be composed entirely of that material. Tu et al. states that when a PTFE blend is used it comprises 95% PTFE, col. 14, lines 15,16. This clearly is a large or significant amount which is considered "essentially" PTFE.

Applicants further argue that the tube of Tu et al.'276 is not distensible such that upon internal pressure it expands 100% larger in circumference than its initial circumference and then remains unchanged. Applicants state the recitation that the Examiner relied on in Tu (col. 10, lines 36-38) is with respect to manufacturing. However, it is noted that Tu, clearly states that this preparation of the tube is suitable for implantation, col. 10, lines 42-48. Applicants further state the interpretation of Tu et al. and the explanation of the tube capabilities of expansion is unreasonable. However, what Applicants fail to appreciate is that Tu et al. present a range of initial diameters for the tube is 4mm, and the expanded range of final diameters include a dimension of 10mm. When a range of measurements is presented it is not limited to having the lower limits to correspond to preliminary and final dimensions having those lower limit

dimensions of the ranges and upper limits solely correspond to preliminary and final diameter measurements presented also in the ranges. Thus, all possible scenarios are clearly within the scope of the disclosure to consider a 4mm diameter expanded to a 10mm diameter. Thus, it does not necessarily mean the 4mm tube is solely expanded only to a 6mm dimension, but clearly can be expanded to 8 or even 10mm.

Applicants further argue that the tube of Tu et al. cannot perform the claimed function of expansion and allege that because it is made differently it does not possess the claimed property. Arguments of a different manufacturing method to make the claimed product as compared with the prior art product does NOT serve to resolve the issue of concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Since the alleged feature said to not be present in either Myers or Tu being a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art. The Examiner possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristics relied on of which clearly both Myers and Tu disclose PTFE tubes with PTFE film as explained above. In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980) (a case indicating that the burden of proof can be shifted to the applicant to show that the subject matter of the prior art does not possess the characteristic relied

on whether the rejection is based on inherency. Applicants provide no evidence of a structural difference in the prior art PTFE tubes. Thus, the prior art tubes possess the same property as claimed or the claims contain insufficient structure for the function to occur because no structural difference is factually shown.

In response to applicant's arguments against the combination of Tu with Eilentropp references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Eilentropp was relied solely for the teaching of helical wrapping material about a tube. Thus, arguments about porosity is irrelevant. Tu was not modified to substitute any material used by Eilentropp, only in the way to form a wrapped tube. Applicants assert there is no reason to combine stating the PTFE of Eilentropp is non-porous and inelastic to suggest it teaches away. However, no recitation of where Eilentropp discussed such features was provided by Applicants to make such an allegation. Regardless Eilentropp stated a conduit for fluid could be provided by the PTFE wrapped tube to maintain fluids within, col. 7, lines 41-43,59,60,68,col. 8, lines 1-3. Thus, since fluid in the form of blood is transported within the tube of Tu et al. it would be obvious to design it to maintain or keep the blood within and prevent leaking. Thus wrapping as taught by Eilentropp would improve that of Tu. With respect to the arguments of porosity, Tu disclosed the PTFE is porous and

since the feature is a relative term, it clearly is not distinguishable as Tu discloses the blood conduit is porous, col. 7, lines 33-42.

Regarding the rejections over Tu '276 combined with either Lee or Hughes, no argument is made the teaching references (Lee and Hughes) fail to teach the claimed limitation. It is argued that the combination does not meet the PTFE tube. As mentioned above, Tu is said to disclose a PTFE tube and PTFE covering of material forming a film as claimed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738